

**Notice of Allowability**

Application No.

09/914,501

Applicant(s)

STRECKFUS ET AL.

Examiner

Anne Holleran

Art Unit

1642

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed 3/8/2005.
2. ☒ The allowed claim(s) is/are 1,2 and 4-14.
3. ☒ The drawings filed on 10 October 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20050601.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard Myers on June 8, 2005.

The application has been amended as follows:

In the claims:

Claim 1. A method of using a salivary biomarker to differentially diagnose carcinoma of the breast in a human test subject, said method comprising:

providing a salivary secretion specimen from a human subject to provide an individual salivary biomarker diagnostic for carcinoma of the breast, said biomarker soluble in said salivary secretion and selected from the group consisting of cancer antigen 15-3, tumor suppressor oncogene protein 53, oncogene c-erbB-2 and combinations thereof;

using the salivary secretion concentration of said individual biomarker to compare with a protein biomarker reference panel, said reference panel including at least one of cancer antigen 15-3, tumor suppressor oncogene protein 53, oncogene c-erbB-2 protein biomarker, [oncogene protein 53 protein biomarker,] and combinations thereof; and

differentially identifying the diagnosis for said subject indicated by said comparison.

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Claim 10. A post-operative method of monitoring the inhibition of breast tumor growth, said method comprising:

providing a human test subject, said subject post-operative to the removal of a malignant breast tumor;

providing a salivary secretion specimen from said subject to develop a post-operative protein biomarker panel, said panel having constituents selected from the group consisting of cancer antigen 15-3, tumor suppressor oncogene protein 53, oncogene c-erbB-2 protein biomarker and combinations thereof;

comparing said post-operative biomarker panel to compare with a pre-operative biomarker reference panel for said subject; and


determining the post-operative inhibition of breast tumor growth by monitoring at least one constituent of said biomarker panels.

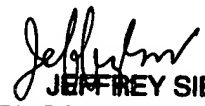
Claim 13. The method of claim 10 wherein said pre-operative and said post-operative panels include a [C-erbB-2] c-erbB2 protein biomarker constituent.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

  
Anne L. Holleran  
Patent Examiner  
June 8, 2005

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER  
6/9/05